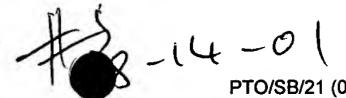
Ml.





0400

Please type a plus sign (+) inside this box -> [+]

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. 09/805,293 **Application Number** TRANSMITTAL March 12, 2001 Filing Date 2001 AUG 0 91 **FORM** Halsted, Charles H. First Named Inventor e used for all correspondence after initial filing) **Group Art Unit** 1645 **Examiner Name Attorney Docket Number** Total Number of Pages in This Submission 023070111710 ENCLOSURES (check all that apply) After Allowance Communication to Assignment Papers Fee Transmittal Form Group (for an Application) Appeal Communication to Board of Fee Attached Drawing(s) Appeals and Interferences Appeal Communication to Group Amendment / Response Licensing-related Papers (Appeal Notice, Brief, Reply Brief) Petition Routing Slip (PTO/SB/69) Proprietary Information After Final and Accompanying Petition Petition to Convert to a Status Letter **Provisional Application** Affidavits/declaration(s) Power of Attorney, Revocation Other Enclosure(s) Extension of Time Request Change of Correspondence Address (please identify below): **Terminal Disclaimer** Return Postcard; Form PTO-1449; PCT Express Abandonment Request Search Report; copies of References cited Request for Refund therein Information Disclosure Statement CD, Number of CD(s) The Commissioner is authorized to charge any additional fees to Certified Copy of Priority Deposit Account 20-1430. Remarks Document(s) Response to Missing Parts/ **Incomplete Application** Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Townsend and Townsend and Crew LLP Firm and Reg No. 35,551 Laurence J. Hyman Individual name Signature Date CERTIFICATE OF MAILING Express Mail Label: EL104786497US I hereby certify that this correspondence is being deposited with the United States Postal Service with "Express Mail Post Office to . 9 2001 and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 Patricia Andrews Typed or printed name

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

indus

Date

SF 1255088 v1

Signature

atmour

Mailed: August 9, 2001

To: Assistant Commissioner for Patents Washington, D.C. 20231

"Express Mail" Label No. EL104786497US
TOWNSEND and TOWNSEND and CREW LLP

Attorney Docket No.: 02307O-111710US
Client Reference No.: 2000-254-1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner:

Art Unit:

§1.98

1645

STATEMENT UNDER 37 CFR §1.97 and

INFORMATION DISCLOSURE

In re application of:

Charles H. Halsted et al.

Application No.: 09/805,293

Filed: March 12, 2001

For: MUTATIONS IN HUMAN GLUTAMATE CARBOXYPEPTIDASE II GENE IMPACTING FOLATE METABOLISM, AND DETECTION OF AFFECTED INDIVIDUALS

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the Search/Examination report to the corresponding PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Application No.: 09/805,293

Page 2

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the abovenoted Deposit Account.

Respectfully submitted,

Laurence J. Hyman Reg. No. 35,551

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8th Floor San Francisco, California 94111-3834 Tel: 415-576-0200

Fax: 415-576-0300

LJH:pja

SF 1254125 v1

ORM PTO-1449 (Modified)		Attorney Docket No.: 02307O-111710US Application No.: 09/805,293				
IST OF PATENTS AND PUB	LICATIONS FOR	Applicant: Charles H. Halsted et al.				
PPLICANT'S INFORMATIO	N DISCLOSURE			1645		
TATEMENT (Use several she	ets if necessary)	Filing Date: March 12,		Group: 1645 Page 1		
eference Designation		U.S. PATENT DOCUMI			Filing Date	
Examiner Initial Document No.	Date	Name	Class	Sub-class	(If Appropriate)	
OIP						
AU6 0 9 2001 \$						
TRANSMARK OFF						
	FO	REIGN PATENT DOC	UMENTS			
		Country	Class	Sub-class	Translation	
Document No	Date				(Yes/No)	
	OTHER ART (In	cluding Author, Title, D	ate, Pertinent Pages	s, Etc.)		
A Devlin et al			which accordated Wit	h inwer ievels ou s	erum folate and	
	- A	AN MANIOPTION LIPTURED. 4.				
1	Halstead et al. "Folypoly-y-glutamate carboxypeptidase from pig jejunum." Journal of Biological Chemistry. 07 August 1998, Vol. 273, No. 32, pages 20417-20424					
C Tiffony et s	August 1998, Vol. 273, No. 32, pages 2017, 2012. Tiffany et al. "Chracterization of the Enzymatic Activity of PSM: Comparison with Brain NAALADase." The Prostate. 01 April 1999, Vol. 39, No. 1, pages 28-35					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT To: LAURENCE J. HYMAN TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER, 8TH FLOOR NOTIFICATION OF TRANSMITTAL OF SAN FRANCISCO, CA 94111-3834 THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION (PCT Rule 44.1) 25 JUN 200° Date of Mailing (day/month/year) Applicant's or agent's file reference See paragraphs 1 and 4 below FOR FURTHER ACTION 23070-11171P International filing date International application No. (day/month/year) 16 APRIL 2001 PCT/US01/07880 Applicant THE REAGENTS OF THE UNIVERSITY OF CALIFORNIA The applicant is hereby notified that the international search report has been established and is transmitted herewith. 1. X Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46): When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet. Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35 For more detailed instructions, see the notes on the accompanying sheet. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made. The applicant is reminded of the following: 4. Further action(s): Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication. Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later). Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks Box PCT

Washington, D.C. 20231

Facsimile No. (703) 305-3230

Form PCT/ISA/220 (July 1998) *

Authorized officer

(703) 308-0 Telephote No.

(See notes on accompanying sheet)



PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 23070-11171P	FOR FURTHER ACTION	(Form PCT/ISA/220	Transmittal of Internationa)) as well as, where applicab	
International application No.	International filing da	te (day/month/year)	(Earliest) Priority Date (da	ty/moiur/yeu/
PCT/US01/07880	16 APRIL 2001		13 MARCH 2000	
Applicant THE REAGENTS OF THE UNIVERS	SITY OF CALIFORNIA			
This international search report has be according to Article 18. A copy is bei	ing transmittee to the		uthority and is transmitted	to the applicant
This international search report consis	er of a total of 2 she	ets.		
This international search report consist X It is also accompanied by a	copy of each prior art d	ocument cited in this	report.	
 Basis of the report a. With regard to the language, 	the international search w	as carried out on the	pasis of the international app	plication in the
language in which it was filed	as carried out on the bas	is of a translation of	the international application	on furnished to this
b. With regard to any nucleotide was carried out on the basis	e and/or amino acid seq	uence disclosed in the	international application, th	e international search
was carried out on the basis contained in the internation		n form.		
X filed together with the int			om.	
furnished subsequently to				
furnished subsequently to	this Authority in compu	iter readable form.	nes not go beyond the disc	losure in the
the statement that the sub- international application	as filed has been furnish	ed.	dentical to the written sequen	ence listing has been
furnished.				
2. Certain claims were for		BOX I).		
3. Unity of invention is la	cking (See Box 11).			
4. With regard to the title,				
X the text is approved as s	submitted by the applican	it.		
the text has been establi	shed by this Authority to	read as follows:		
5. With regard to the abstract,	submitted by the applica	nt.		
Box III. The applicant r	ished, according to Rule may, within one month fromments to this Authoric	38.2(b), by this Authom the date of mailingly.	•	
6. The figure of the drawings to	be published with the ab	estract is Figure No.		
as suggested by the ap			X	None of the figures
	failed to suggest a figure	•		
	ter characterizes the inve			

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/07880

IPC(7) :0	SIFICATION OF SUBJECT MATTER C12Q 01/68; G01N 33/53; C07H 21/04 35/6, 7.4; 536/23.5		
	International Patent Classification (IPC) or to both national	onal classification and IPC	
	OS SEARCHED	1	
	cumentation searched (classification system followed by	classification symbols)	
U.S. : 4	35/6, 91.2; 7.47.9, 7.92; 536/23.5, 24.32, 24.33		
	on searched other than minimum documentation to the exte		
Electronic de	ata base consulted during the international search (name	of data base and, where practicable	e, search terms used)
	EDLINE, EMBASE, BIOSIS, CAPLUS amate carboxypeptidase, polymorphism		·.
C. DOC	JMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appro	priate, of the relevant passages	Relevant to claim No.
X,P	DEVLIN et al. Glutamate carboxypepti associated with lower levels of hyperhomocysteinemia. Human Molecula 2000, Vol. 9, No. 19, pages 2837-2844,		
A	HALSTEAD et al. Folypoly-γ-glutamate jejunum. Journal of Biological Chemistr 273, No. 32, pages 20417-20424, see en	1-30	
A	TIFFANY et al. Characterization of the E Comparison with Brain NAALADase. The Vol. 39, No. 1, pages 28-35, see entire	1-30	
i			
			₹ . •
T 5:01	ner documents are listed in the continuation of Box C.	See patent family annex.	s.
	ecial categories of cited documents:	later document published after the i	nternational filing date or priority
•A• do	cument defining the general state of the art which is not considered	date and not in conflict with the arther principle or theory underlying	the invention
to be of particular relevance "X" document of particular relevance; to document of particular relevance.			the claimed invention cannot be dered to involve an inventive step
ci	ocument which may throw doubts on priority claim(s) or which is ted to establish the publication date of another citation or other		the claimed invention cannot be
.O. q	ecial reason (as specified) cument referring to an oral disclosure, use, exhibition or other	considered to involve an invention combined with one or more other a being obvious to a person skilled it	ve step when the document is uch documents, such combination
•P• d	cans ocument published prior to the international filing date but later than ego priority date claimed		
		Date of mailing of the international	
04 JUNI		25 JUN 20	01
Box PCT	oner of Patents and Trademarks on, D.C. 20231	LISA ARTHUR Celephone No. (703) 308-0196	gers for

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter IL

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- . (i) the claim is unchanged;
 - (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.